IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ABBOTT LABORATORIES and FOURNIER LABORATORIES IRELAND LTD., Plaintiffs, v. IMPAX LABORATORIES, INC., Defendant.	C.A. No. 2:10-cv-01322-DMC-JAD Hon. Dennis M. Cavanaugh, U.S.D.J. Hon. Joseph A. Dickson, U.S.M.J.
ABBOTT LABORATORIES and FOURNIER LABORATORIES IRELAND LTD., Plaintiffs, v. LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC., Defendants.	C.A. No. 2:10-cv-01578-DMC-JAD Hon. Dennis M. Cavanaugh, U.S.D.J. Hon. Joseph A. Dickson, U.S.M.J.
ABBOTT LABORATORIES and FOURNIER LABORATORIES IRELAND LTD., Plaintiffs, v. MYLAN PHARMACEUTICALS INC. and MYLAN INC., Defendants.	C.A. No. 2:10-cv-02073-DMC-JAD Hon. Dennis M. Cavanaugh, U.S.D.J. Hon. Joseph A. Dickson, U.S.M.J.

ABBOTT LABORATORIES and FOURNIER LABORATORIES IRELAND LTD., Plaintiffs, v. WATSON LABORATORIES, INC.-FLORIDA, WATSON PHARMA, INC., and WATSON PHARMACEUTICALS, INC., Defendants.	C.A. No. 2:10-cv-02139-DMC-JAD Hon. Dennis M. Cavanaugh, U.S.D.J. Hon. Joseph A. Dickson, U.S.M.J.
ABBOTT LABORATORIES and FOURNIER LABORATORIES IRELAND LTD., Plaintiffs, v. ACTAVIS ELIZABETH LLC and ACTAVIS INC., Defendants.	C.A. No. 2:10-cv-02352-DMC-JAD Hon. Dennis M. Cavanaugh, U.S.D.J. Hon. Joseph A. Dickson, U.S.M.J.
ABBOTT LABORATORIES and FOURNIER LABORATORIES IRELAND LTD., Plaintiffs, v. ANCHEN PHARMACEUTICALS INC., Defendant.	C.A. No. 2:10-cv-03015-DMC-JAD Hon. Dennis M. Cavanaugh, U.S.D.J. Hon. Joseph A. Dickson, U.S.M.J.

ABBOTT LABORATORIES and FOURNIER LABORATORIES IRELAND LTD., Plaintiffs, v. WATSON LABORATORIES, INC.-FLORIDA, WATSON PHARMA, INC., and WATSON PHARMACEUTICALS, INC., Defendants.	C.A. No. 2:10-cv-03241-DMC-JAD Hon. Dennis M. Cavanaugh, U.S.D.J. Hon. Joseph A. Dickson, U.S.M.J.

DEFENDANTS' RESPONSIVE CLAIM CONSTRUCTION BRIEF

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'186 patent	U.S. Patent No. 7,259,186
Chin Ex. __	Exhibits A-K: The corresponding exhibit to the Declaration of Roger J. Chin in Support of Defendants' Opening Claim Construction Brief, filed February 4, 2011
	Exhibits L-M: The corresponding exhibit to the Supplemental Declaration of Roger J. Chin in Support of Defendants' Responsive Claim Construction Brief, filed concurrently herewith
Defs. Br.	Defendants' Opening Claim Construction Brief, filed February 4, 2011
Pls. Br.	Opening Claim Construction Brief of Plaintiffs Abbott Laboratories and Fournier Laboratories Ireland, Ltd., filed February 4, 2011
__:__	The column and line numbers, respectively, of a U.S. patent

I. INTRODUCTION

In the '186 patent, the patentees clearly outlined the bounds of their claimed invention. They specified that the claims are directed to "a pharmaceutical formulation in a form of a molecular dispersion," and that the molecular dispersion includes a binder component that is carefully described in the patent specification.

It is far too late for the patentees to have second thoughts about what they told the patent examiner and the public in the '186 patent. The public is entitled to rely on the notice function of the patent, and in this case, that notice function is served by giving credit to the patentees' own characterization of the "present invention" as including a "molecular dispersion"; the description of the "binder component" in accordance with the patent specification; and the express distinction between "enteric binders" and "non-enteric binders."

Claim construction will be dispositive of these lawsuits. None of the defendants' products have a "molecular dispersion," nor do any defendants utilize the specialized techniques described in the patent for manufacturing a molecular dispersion. None of the defendants' products have a "binder component" that is an "enteric binder." In order to overcome these obstacles, plaintiffs have turned to a strategy of either ignoring the claim limitations altogether (*e.g.*, "molecular dispersion") or leaving the factual determination of infringement untethered to any substantive claim construction (*e.g.*, "binder component"). *Markman* and its progeny specifically intended to rein in such tactics. Litigation should not provide plaintiffs an opportunity to obtain patent coverage over what they failed to distinctly claim and describe in the '186 patent.

II. ARGUMENT

A. "Pharmaceutical Formulation in a Form of a Molecular Dispersion"

Defendants' Construction	Plaintiffs' Construction
A system in which at least part and particularly the predominant part of the individual molecules of the salt of fenofibric acid are homogeneously dispersed in the binder component, and the dispersed substance is free of interfaces.	A pharmaceutical formulation in which at least part and particularly the predominant part of the fenofibric acid content, is homogeneously dispersed in the binder component, and the dispersed substance is free from interfaces.
Defendants contend that this preamble recites a structural limitation.	Plaintiffs contend that this preamble does not recite a structural limitation.

1. The Preamble Recites a Structural Limitation

As defendants demonstrated in their opening brief, the preamble gives meaning to the claims and therefore serves as a claim limitation. Defs. Br. at 4-7.

Plaintiffs counter by asserting that "[g]enerally, the preamble does not limit the claims." Pls. Br. at 3. Such generalizations are of no relevance here. Whether a preamble limits the claim must be "determined on the facts of each case in light of the claim as a whole and the invention described in the patent." *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 952 (Fed. Cir. 2006) (citations omitted). Thus, plaintiffs' characterization about the "general" role of preambles is, at best, "descriptive rather than prescriptive." *Bell Commc'ns Research, Inc. v. Vitalink Commc'ns Corp.*, 55 F.3d 615, 621 (Fed. Cir. 1995). As the Federal Circuit observed, "it is not unusual for this court to treat preamble language as limiting." *Bicon*, 441 F.3d at 952.

a. The Preamble Is Limiting Because It Sets Forth Structural Features of the Claimed Invention

The parties agree that the "molecular dispersion" described in the preamble includes at least the following structural elements:

- the active ingredient is "homogenously dispersed in the binder component"; and
- "the dispersed substance is free of interfaces."

These requirements are not merely statements of "purpose or intended use." Rather, they set forth structural features of the claimed pharmaceutical formulation that limit the claims. *See Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997) ("Where a patentee uses the claim preamble to recite structural limitations of his claimed invention, the PTO and courts give effect to that usage."); *Bicon*, 441 F.3d at 952 ("the preamble of claim 5 is not limited to stating the purpose or intended use of the invention, but contains structural features of the abutment"); *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1539 (Fed. Cir. 1991) (shank configuration described in preamble "is not merely a suggested use or 'clarifying language,' as London argues, but rather a limitation supported by structure which must be satisfied" to be infringed).

Plaintiffs conspicuously fail to include this factor among the "guideposts" that they selectively identify in their opening brief. Specifically, plaintiffs borrow their guideposts from *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801 (Fed. Cir. 2002). Pls. Br. at 4. In a portion of that case that plaintiffs neglect, however, *Catalina Marketing* explains the basis for distinguishing between limiting structural features versus nonlimiting statements of purpose or intended use: "the patentability of apparatus or composition claims depends on the claimed structure, not on the use or purpose of that structure." *Id.* at 809. Therefore, a preamble may not be limiting if "deletion of the preamble phrase does not affect the structure or steps of the claimed invention." *Id.* Plaintiffs fail this test. Deletion of the preamble substantially affects the structure of the claimed invention, because without it, the claim merely recites an arbitrary collection of materials without the structural requirement of a molecular dispersion.

b. A Molecular Dispersion Is Part of the Invention Described in the Patent Specification

"Whether to treat a preamble as a limitation is a determination resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim." *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1347 (Fed. Cir. 2002). Defendants demonstrated in their opening brief that the preamble is limiting because the patent specification describes the molecular dispersion as integral to the invention. Defs. Br. at 6-7. Indeed, the "molecular dispersion" is mentioned no fewer than sixteen times in the patent specification. Chin Ex. A at Abstract, 1:29, 2:33, 3:17-18, 5:47, 9:4, 9:5, 9:10, 9:26, 9:33, 9:37, 9:40, 9:43, 11:12, 14:26, 20:37. The patent specification describes the characteristics of the molecular dispersion (*id.* at 9:9-11, 9:26-28); identifies analytical methods used to investigate the molecular dispersion (*id.* at 9:33-42); explains how molecular dispersions are manufactured (*id.* at 14:24-28); and warns against using excipients that could impair the formation of a molecular dispersion (*id.* at 11:9-12). *See generally* Defs. Br. at 7.

It is undisputed that the patent specification describes, repeatedly and in considerable detail, that the pharmaceutical formulation is in the form of a molecular dispersion. Nevertheless, plaintiffs search the interstices of the patent to identify an embodiment that, supposedly, does not require a molecular dispersion. In particular, plaintiffs contend that column 2, lines 21-29, of the '186 patent describe a "complete invention" without a molecular dispersion. *See* Pls. Br. at 5. This passage provides no assistance to plaintiffs' position.

First, plaintiffs improperly support their "complete invention" argument by presenting an incomplete quotation from the patent. In order to advance their argument, plaintiffs cropped out the last two sentences of the relevant passage. Not coincidentally, those sentences explain that

the formulation is in the form of a molecular dispersion.[1] That passage, including the cropped portion that plaintiffs omit from their brief, is set forth below:

> In one aspect, the present invention relates to a pharmaceutical formulation comprising:
>
> i) fenofibric acid, or a physiologically acceptable salt or derivative thereof and optionally, other active ingredients (which is collectively referred to as the "active substance component);
>
> ii) a binder component comprising at least one enteric binder; and optionally,
>
> iii) other physiologically acceptable excipients.
>
> The physiologically acceptable derivative of fenofibric acid can be fenofibrate. Additionally, the fenofibric acid, physiologically acceptable salt or derivative thereof can be present in the formulation as a molecular dispersion.

Chin Ex. A at 2:21-33 (emphasis added); *compare* Pls. Br. at 5.

Second, to the extent that plaintiffs' cropped passage describes a "complete invention" without a molecular dispersion, such description does not relate to the claims that actually issued in the '186 patent. The prosecution history of the '186 patent demonstrates that the cropped passage cited in plaintiffs' opening brief corresponds nearly verbatim to a claim that was ultimately abandoned by the patentees; whereas the passage cited in defendants' opening brief corresponds nearly verbatim to issued claim 8 of the '186 patent. The following diagram illustrates this progression:

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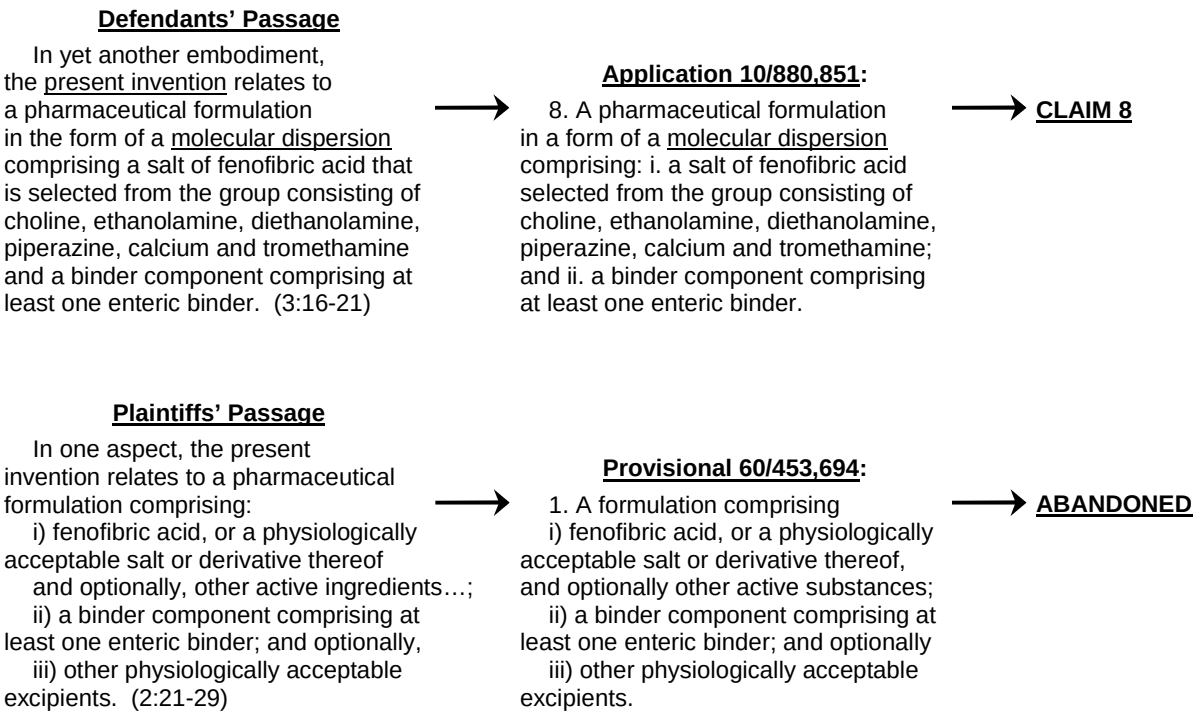
[1] Plaintiffs alternatively include a citation to column 3, lines 39-47. *See* Pls. Br. at 5. This passage fares no better. That passage begins by describing a mixture of three components (fenofibric acid, binder component, and excipients). Chin Ex. A at 3:39-47. However, that passage is immediately followed by a corresponding discussion of each of the three components. *Id.* at 3:49 (fenofibric acid), 5:38 (binder component), 9:58 (excipients). The accompanying discussion of the binder component explains that it takes up the "active substance which is in the form of a molecular dispersion." *Id.* at 5:45-46.



See Chin Ex. A at 3:16-21 (Defendants' Passage) (emphasis added); Chin Ex. L at 50 (App. No. 10/880,851, claim 8) (emphasis added); Chin Ex. A at 35:16-22 ('186 patent, claim 8); *id.* at 2:21-29 (Plaintiffs' Passage); Chin Ex. M at 29 (Provisional No. 60/453,694, claim 1).

As the above diagram reveals, the passage cited by defendants – which states that "the present invention relates to a pharmaceutical formulation in the form of a molecular dispersion" – corresponds directly to claim 8 of the '186 patent, which is at issue in these claim construction proceedings. By contrast, the passage cited by plaintiffs corresponds to a claim that was advanced earlier in the prosecution history, in Provisional Application No. 60/453,694. However, the patentees did not pursue that claim and, instead, abandoned the provisional application. 35 U.S.C. § 111(b)(5). Thus, to the extent that column 2, lines 21-29, of the patent allegedly defines a broader "complete invention" without a molecular dispersion, the claims cannot be so broadly construed because the patentees made a deliberate decision not to claim it. *See Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1289 (Fed. Cir. 2009) ("Thus, Abbott knew

exactly how to describe and claim Crystal B compounds. Knowing of Crystal B, however, Abbott chose to claim only the A form in the '507 patent."); *see also Unique Concepts, Inc. v. Brown*, 939 F.2d 1558, 1562 (Fed. Cir. 1991).[2]

c. The Preamble Is Limiting Because It Provides Meaning to the Claims

Under plaintiffs' own "guidepost," a preamble is limiting where it provides an antecedent basis for language in the body of a claim. Pls. Br. at 4. The preamble serves such a role here. Specifically, the body of claims 14 and 15 of the '186 patent refer to the previously introduced "formulation" of claim 8.[3] Chin Ex. A at 35:15-22. In order to provide context for "the formulation" recited in these claims, it is necessary to give meaning to the antecedent language found in the preamble that introduces the formulation as being "in the form of a molecular dispersion."[4]

d. The Narrower Construction Is Favored to Ensure Adequate Notice to the Public

The patentees had an obligation during prosecution to distinctly claim their invention, 35 U.S.C. § 112 ¶ 2, and they were free to select appropriate claim language as they saw fit. In this case, the patentees elected to include a preamble with structural features that are described

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[2] Merely because an alternative embodiment is described in the patent specification does not mean that it falls within the scope of the claims. *See Baran v. Med. Device Techs., Inc.*, 616 F.3d 1309, 1316 (Fed. Cir. 2010) ("It is not necessary that each claim read on every embodiment.").

[3] Use of the definite article ("the formulation") in claims 14 and 15 necessarily refers back to the previously introduced "formulation" of claim 8. 2 Patent Practice § II.C.3.c at 10-18 (5th ed. 1993) (Chin Ex. K).

[4] This is not a case where the language can be limiting in one claim and not the other. Here, the preamble found in claim 8 is incorporated by reference into claims 14 and 15. Thus, the very same preamble (from claim 8) applies to each of claims 8, 14 and 15. The preamble cannot be limiting and nonlimiting at the same time.

as part of the "present invention." Under these circumstances, "[a]llowing a patentee to argue that physical structures and characteristics specifically described in a claim are merely superfluous would render the scope of the patent ambiguous, leaving examiners and the public to guess about which claim language the drafter deems necessary to his claimed invention and which language is merely superfluous, nonlimiting elaboration." *Bicon*, 441 F.3d at 950.

Even if there were a basis to adopt plaintiffs' broader proposed construction, the notice function of the patent is best served by adopting a narrower construction that includes the "molecular dispersion" requirement from the preamble. As between the public and the patentees, the patentees must bear the risk of ambiguity in the claim language. Thus, between two reasonable constructions, the narrower one should be adopted:

> Where there is an equal choice between a broader and a narrower meaning of a claim, and there is an enabling disclosure that indicates that the applicant is at least entitled to a claim having the narrower meaning, we consider the notice function of the claim to be best served by adopting the narrower meaning.

Athletic Alternatives, Inc. v. Prince Mfg., Inc., 73 F.3d 1573, 1581 (Fed. Cir. 1996); *see also Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1344 (Fed. Cir. 1998); *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 93 F.3d 1572, 1581 (Fed. Cir. 1996) ("to the extent that the claim is ambiguous, a narrow reading which excludes the ambiguously covered subject matter must be adopted").

2. Defendants' Construction Should Be Adopted

The only substantive difference between the parties' constructions turns on whether the homogenously dispersed ingredient comprises "the individual molecules of the salt of fenofibric acid." *See* Defs. Br. at 8.

Plaintiffs defend their proposed definition by mechanically adhering to language from column 9 to define a "molecular dispersion." Pls. Br. at 7. That language refers to an unspecified "fenofibric acid content" being homogenously dispersed in the binder component. After proposing the language from column 9, however, plaintiffs refuse to allow for any further construction. This leaves the phrase "fenofibric acid content" undefined, thereby deferring the dispute for another day and inviting experts to improperly opine on claim construction. Such an approach is an invitation to error. *See CytoLogix Corp. v. Ventana Med. Sys., Inc.*, 424 F.3d 1168, 1172 (Fed. Cir. 2005).

The cases cited by plaintiffs merely stand for the proposition that a patentee may act as a lexicographer by including definitional language in the patent specification. Defendants do not dispute that proposition of law. However, the case law does not require the Court to adopt the language "word for word" without further elaboration, as plaintiffs propose. Pls. Br. at 8. To the contrary, even definitional language set forth in the patent specification may require further construction. *See Abraxis Bioscience, Inc. v. Mayne Pharma (USA) Inc.*, 467 F.3d 1370, 1376-78 (Fed. Cir. 2006) (patent specification defined "edetate" as including "derivatives"; court further construed "derivatives" to exclude structural analogs).

Defendants' proposal is entirely consistent with the definition language found in column 9. The difference is that defendants provide further clarification regarding the "fenofibric acid content" in the molecular dispersion of claim 8. Indeed, the patent specification affirmatively invites further clarification.

Significantly, the '186 patent indicates that the meaning of "molecular dispersion" is "known to one skilled in the art." Chin Ex. A at 9:6. The technical definition of "molecular dispersion" (which plaintiffs do not dispute[5]) is as follows:

> **molecular dispersion**: dispersion in which the dispersed phase consists of individual molecules; if the molecules are of less than colloidal size, the result is a true solution.

Stedman's Med. Dictionary at 528 (27th ed. 2000) (Chin Ex. I) (emphasis added). This definition may appropriately be used for claim construction because it is consistent with (and sheds further light on) the description found in the patent specification. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1322-23 (Fed. Cir. 2005) ("judges are free to consult dictionaries and technical treatises at any time in order to better understand the underlying technology and may also rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents") (citation omitted).

The passage in column 9 explains, as part of the definition, that "as used herein" the term "molecular dispersion" is "known to one skilled in the art." Chin Ex. A at 9:5-6. This statement instructs the reader to utilize such available knowledge – that a "molecular dispersion" requires a dispersion of "individual molecules" – to understand the corresponding claim language. Thus, when read in the context of claim 8, which calls for "a salt of fenofibric acid," the "fenofibric acid content" in the form of a "molecular dispersion" of column 9 must refer to "the individual molecules of the salt of fenofibric acid."

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[5] Defendants identified this definition pursuant to Local Patent Rule 4.2(b), well over a month prior to claim construction briefing. Chin Ex. E at 4. In their opening brief, plaintiffs do not question the accuracy of this definition, nor do they offer any contrary evidence of a meaning of "molecular dispersion" that is "known to one skilled in the art."

B. "Binder Component"

Defendants' Construction	Plaintiffs' Construction
A matrix forming excipient in which the individual molecules of the salt of fenofibric acid are embedded and homogeneously dispersed, thereby forming a solid solution of the active substance in the binder.	Ordinary meaning (*i.e.*, "A pharmaceutically acceptable binder")

Plaintiffs contend that "binder component" need not be construed because it is only used in its "general sense" throughout the patent. Pls. Br. at 9. However, plaintiffs fail to identify what that "general sense" is, other than circularly proposing that a "binder component" includes a "binder." *Id.* Refusing to define a claim term beyond its "general sense" is improper because the claims "do not have meaning removed from the context from which they arose." *Network, LLC v. Centraal Corp.*, 242 F.3d 1347, 1352 (Fed. Cir. 2001).

The term "binder component" is a technical term used in the pharmaceutical industry. Therefore, the failure to provide a substantive construction shifts the responsibility for interpreting this language to experts who will testify about the issue of infringement. Plaintiffs' experts would first analyze defendants' products, and based on that analysis, determine whether they have a binder component in the "general sense." This tactic turns the infringement analysis on its head. Claims must be construed before they are compared with the accused product. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370 (1996). Thus, when the parties present a dispute regarding the scope of the claims, it is the Court's duty under *Markman* to provide a construction. *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008).

As demonstrated in their opening brief, defendants' proposed construction is based directly on the patent specification. The '186 patent describes certain essential characteristics of a "binder component":

> The binder component of the formulations of the present invention may also be understood to include a binder which at least in part forms a binder matrix, particularly, a polymer matrix, in which the active substance is embedded. Binders suitable for use in the present invention include, solid meltable solvents. The binder matrix serves to take up and, especially, to dissolve at least part of the active substance component, especially the fenofibric acid content. To this extent, the binder is also a solvent. In relation to the active substance which is in the form of a molecular dispersion and dissolved, it is possible to speak of a solid solution of the active substance in the binder, the binder being either in crystalline form or in amorphous form.

Chin Ex. A at 5:38-50 (emphasis added). Defendants' proposed construction incorporates these requirements. *See* Defs. Br. at 11.

Although the foregoing passage is not in "X means Y" format, no such rigid formalism is required for the specification to inform the proper construction. *Astrazeneca AB v. Mutual Pharm. Co.*, 384 F.3d 1333, 1339 (Fed. Cir. 2004); *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Group, Inc.*, 262 F.3d 1258, 1271 (Fed. Cir. 2001) ("the written description can provide guidance as to the meaning of the claims, thereby dictating the manner in which the claims are to be construed, even if the guidance is not provided in explicit definitional format") (citation omitted). The passage of column 5 quoted above is the only passage in the '186 patent that substantively describes the characteristics of a binder component. As such, it plays a critical role to understanding the meaning of "binder component." "[T]he specification is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315. The specification thus dictates the proper construction of the claims. *On Demand Mach. Corp. v. Ingram Indus., Inc.*, 442 F.3d

1331, 1340 (Fed. Cir. 2006) ("the claims cannot be of broader scope than the invention that is set forth in the specification").

The language of column 5 further confirms that it is describing necessary characteristics of a binder component. *See, e.g.*, Chin Ex. A at 5:39 ("understood to include"); *id.* at 5:43 ("binder matrix serves to"); *id.* at 5:46 ("the binder is"); 5:49 ("the binder being"). The passage does not include any caveat that the described binder component is only a preferred embodiment. Indeed, those features that are characterized as "preferred" are set off in the subsequent paragraph (lines 51-59), which is separately introduced by the transition: "Preferably, the binder component…" By contrast, the characteristics of a binder component set forth in lines 38-50 (and upon which defendants rely) are not so limited.

Plaintiffs offer no evidence that "binder component" should be construed more broadly than as described in the patent specification. Instead, plaintiffs sole criticism is that the passage in question is qualified by the word "may." Pls. Br. at 9. The word "may" is not a free pass to ignore the patent specification. *See Eisenberg v. Alimed, Inc.*, 243 F.3d 555 (table), 2000 WL 1119743, at *3 (Fed. Cir. 2000) (statement that an element "may be flexible" does not make flexibility optional; "this gives undue weight to the isolated word 'may'"). Equivocal phraseology "does not of itself broaden the claims beyond their support in the specification." *Wang Labs., Inc. v. America Online, Inc.*, 197 F.3d 1377, 1383 (Fed. Cir. 1999).

The suggestion that there is a broader "ordinary meaning" of "binder component" fares no better. Pls. Br. at 10. Plaintiffs fail to identify any evidence that there exists an "ordinary meaning" that is any broader than the binder component described in the patent specification. *See* Local Patent R. 4.2(b). With no contrary evidence presented, the patent specification serves as the best – and only – evidence of the meaning of "binder component."

C. "Enteric"

Defendants' Construction	Plaintiffs' Construction
Resistant to solution in acidic gastric fluid but disintegrable in the more alkaline environment of the intestine.	No construction is needed as "enteric" is only used in the claims within the phrases "enteric polymer" and "enteric binder," which are already being construed.[6]

Over a month before claim construction, defendants identified a widely-recognized pharmaceutical treatise that sets forth a definition of "enteric." *See* Remington's Pharm. Sci. at 1634 (18th ed. 1990) (Chin Ex. J) ("enteric" refers to "substances that resist solution in gastric fluid but disintegrate in the intestine"). Plaintiffs neither question the accuracy of this definition, nor offer any contrary definition of that term. On this basis alone, defendants' definition should be adopted.

Plaintiffs' only basis for a contrary construction is that the word "enteric" is used within the phrase "enteric polymer." Pls. Br. at 12-13. While defendants do not dispute that "enteric polymer" serves to further limit the scope of claim 10, it is error to conflate the definition of the term "enteric" with the definition of a phrase in which that word appears. *See* Defs. Br. at 12-13; *cf. Fed. Commc'ns Comm'n v. AT&T Inc.*, __ U.S. __, 2011 WL 691243, at *4 (Mar. 1, 2011) ("there may well be a link between the noun and the adjective" but "in ordinary usage, a noun and its adjective form may have meanings as disparate as any two unrelated words").

[6] Plaintiffs' alternative position is that "[i]f a construction is necessary, it should be consistent with the use of enteric in the agreed upon construction of 'enteric polymer' – namely, enteric is an adjective that describes something that is 'preferentially soluble in the less acid environment of the intestine relative to the more acid environment of the stomach.'"

D. "Enteric Binder"

Defendants' Construction	Plaintiffs' Construction
A binder, the solubility or swellability of which increases with increasing pH and vice versa, and excluding the nonenteric binders identified at column 7, line 59 - column 8, line 33.	A binder, the solubility or swellability of which increases with increasing pH and vice versa.

The '186 patent identifies a list of "non-enteric binders" that, as a matter of law, fall outside the scope of the claimed "enteric binders." *See, e.g., Asyst Techs., Inc. v. Emtrak, Inc.*, 402 F.3d 1188, 1195 (Fed. Cir. 2005) ("the term 'mounted' can fairly be said to specifically exclude objects that are 'unmounted'"); *Moore U.S.A., Inc. v. Standard Register Co.*, 229 F.3d 1091, 1106 (Fed. Cir. 2000) ("it would defy logic to conclude that a minority – the very antithesis of a majority – could be insubstantially different from a claim limitation requiring a majority, and no reasonable juror could find otherwise"). Significantly, plaintiffs agree that non-enteric binders are outside the scope of the claimed "enteric binders":

> Plaintiffs do not dispute that non-enteric binders are outside of the proper construction of enteric binders.

Pls. Br. at 11. The Court should adopt defendants' proposed construction, which excludes subject matter that plaintiffs concede is "outside of the proper construction of enteric binders." *Ballard Med. Prods. v. Allegiance Healthcare Corp.*, 268 F.3d 1352, 1359 (Fed. Cir. 2001) (specification may be used "to define what his invention is and what it is not") (emphasis added).

Plaintiffs raise only one objection to defendants' proposed construction. According to plaintiffs, "the specification does not state that all of the binders on the list at 7:59-8:33 of the '186 patent are non-enteric." Pls. Br. at 11. This assertion is not based on any evidence of record, but rather, is a figment of attorney argument.

The language used by the patentees to identify the non-enteric binders follows a standard format frequently used in patent drafting:

> … said other (non-enteric) binder … [is] selected from the group consisting of …

Chin Ex. A at 7:57-59 (emphasis added). When used in claims, this format is referred to as a "Markush" group:

> A Markush-type claim recites alternatives in a format such as "selected from the group consisting of A, B and C."

M.P.E.P. § 803.02 (emphasis added). When such language is invoked, the members of the identified group "ordinarily must belong to a recognized physical or chemical class or to an art-recognized class." *Id.* Here, the '186 patent identifies that "recognized physical or chemical class" as "non-enteric binders." The public is entitled to rely on the patentees' representation that the members of the group are "non-enteric binders."

The patent specification clearly identifies separate and non-overlapping lists of enteric binders (6:46-7:29) and non-enteric binders (7:59-8:33). Having separately identified non-enteric binders, the patentees have excluded such binders from the scope of the claims. *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001).

III. CONCLUSION

For the reasons set forth above and in their opening brief, defendants respectfully request the Court to adopt defendants' proposed constructions of the disputed claim terms.

Dated: March 11, 2011

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APPENDIX A.
Proposed Claim Constructions

Claim Term	Defendants' Construction	Plaintiffs' Construction
pharmaceutical formulation in a form of a molecular dispersion	A system in which at least part and particularly the predominant part of the individual molecules of the salt of fenofibric acid are homogeneously dispersed in the binder component, and the dispersed substance is free of interfaces. Defendants contend that this preamble recites a structural limitation.	A pharmaceutical formulation in which at least part and particularly the predominant part of the fenofibric acid content, is homogeneously dispersed in the binder component, and the dispersed substance is free from interfaces. Plaintiffs contend that this preamble does not recite a structural limitation.
binder component	A matrix forming excipient in which the individual molecules of the salt of fenofibric acid are embedded and homogeneously dispersed, thereby forming a solid solution of the active substance in the binder.	Ordinary meaning (*i.e.*, "A pharmaceutically acceptable binder")
enteric	Resistant to solution in acidic gastric fluid but disintegrable in the more alkaline environment of the intestine.	No construction is needed as "enteric" is only used in the claims within the phrases "enteric polymer" and "enteric binder," which are already being construed.
enteric binder	A binder, the solubility or swellability of which increases with increasing pH and vice versa, and excluding the nonenteric binders identified at column 7, line 59 - column 8, line 33.	A binder, the solubility or swellability of which increases with increasing pH and vice versa.
enteric polymer	A pH-sensitive polymer which is preferentially soluble in the less acid environment of the intestine relative to the more acid environment of the stomach. (*agreed*)	

Source: Chin Ex. F-H

APPENDIX B.
Relevant Claims of the '186 Patent

Claim 8

A pharmaceutical formulation in a form of a molecular dispersion comprising:

i. a salt of fenofibric acid selected from the group consisting of choline, ethanolamine, diethanolamine, piperazine, calcium and tromethamine; and

ii. a binder component comprising at least one enteric binder.

Claim 10

The formulation as claimed in claim 8, wherein the enteric binder is an enteric polymer.

Source: Chin Ex. A at 35:16-22, 36:1-2